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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/553,937	09/21/2006	Kalman Hideg	67789-485	6143

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EXAMINER	
CHU, YONG LIANG	

ART UNIT	PAPER NUMBER
1626	

MAIL DATE	DELIVERY MODE
12/21/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/553,937	HIDEG ET AL.	
	Examiner	Art Unit	
	Yong Chu	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 October 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *14-28 and 33-35* is/are pending in the application.

4a) Of the above claim(s) *27,28,33 and 34* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14-26 and 35* is/are rejected.

7)☒ Claim(s) *14-26 and 35* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim 35 is new by the Amendment filed on 10/22/2007. Claims 14-28, and 33-35 are pending in this application. Claims 27-28, and 33-34 have been withdrawn by Applicant as non-elected subject matter due to restriction requirement. Therefore, claims 14-26 and 35 will be examined on the merits.

Response to Amendment

The Amendment by Applicants' representative Ms. Linda B. Truong dated on 10/22/2007 has been entered.

Response to Arguments

Specification

The objection to missing the continuation data at 1st paragraph of the Specification has been withdrawn because such amendment was filed on 10/20/2005.

The objection to the title for using "New" has been withdrawn, because applicant has amended the title by removal of the term "New".

The argument regarding the format of abstract has been considered, and is found persuasive. Therefore, the objection to the abstract has been withdrawn.

Claim Objections

The objection to claims 19-24 as being a substantial duplicate of claim 2 has been withdrawn because claim 2 has been canceled.

The objection to claims 14-26 as being containing non-elected subject matter is maintained because the claims contains the non-elected subject matter such as **Y** as an alkene, a carbonyl-amino-C_{1-4}alkene, ..etc. Please refer the search and elected scope of invention in the previous Office action dated on 10/22/2007.

Rejection of claims under 35 U.S.C.§112, 1st paragraph

Applicant's amendment of claims 19-23 does not overcome the rejection under 35 U.S.C.§112, 1st paragraph for failing to comply with written description requirement. Even though there is a word disclosure of the phrase "based on PARP activation and/or are caused by Reactive Oxidative Species (ROS) and Reactive Nitrogen Species (RNS)" on page"11 of the Specification, with specific diseases as examples such as coronary disease, ischemia, inflammation .." on page 11 of the specification, the specification does not described all the diseases which may be associated with the PARP activation and/or diseases caused by ROS and RNS. There are many diseases based on PARP, ROS, and RNS. By definition, PARP is a poly(ADP-ribose)polymerase enzyme, which involved in a number of cellular processes involving mainly DNA repair and programmed cell death. The PARP family comprises 17 members, and they are all very different in structures and functions in the cell (see Wikipedia encyclopedia). The compounds interact with the PARP enzyme with different mechanisms due to the difference of each PARP family enzyme. It is not obvious to one skilled in the art to understand the individual compound enzyme interaction, and related diseases. To comply with written description requirement, the instant specification needs to describe clearly which sub-family PARP enzyme the claimed compounds interact with so that

appropriate diseases can be identified, to demonstrate applicant's possession of the invention. Without the fully written description, it is not clear to one skilled in the art which disease the claimed composition are intended to be used for treating the diseases. It also applies to the treatment of RNS and ROS related disease by using the claimed composition. Therefore, the rejection is maintained.

To overcome the rejection, Applicant needs to cancel the intended to use phase "that is based on PARP activation and/or are caused by reactive Oxidative Species (ROS) and Reactive Nitrogen Species (RNS)", because recitation of an intended to use or utility in the preamble which can otherwise stand alone is not considered a further limitation of the claim and therefore cannot impart patentability to a known composition of matter. See, in re Spada, 15 USPQ.2d 1655 (Fed. Cir. 1990).

Rejection of claims under 35 U.S.C.§103(a)

Applicant's arguments over the rejection have been fully considered, but are found not persuasive. Applicant's argument on the ground that Lubisch et al. only teaches a single substitution on the piperidine, and Lubisch et al. do not teach or suggest using a tetramethyl substitution on the piperidine ring. Furthermore, Applicant argued that the tetramethyl substitution is important because sterically hindered amines and their oxidized derivatives are capable of antioxidant function (See e.g. Specification, page 4).

In response to applicant's argument that the prior art only teaches a single substitution on the piperidine, and Lubisch et al. do not teach or suggest using a tetramethyl substitution on the piperidine ring, the Examiner would like to draw

Applicant's attention to the 2nd paragraph, page 7 of the previous Office action, "the `271 patent claim 3 specifically define that **A** may be piperidine and substituted with $C_1$-$C_4$alkyl." According to the `271 patent (i.e. Lubisch et al.), the C_1-C_4alkyl could be multiple, which clearly suggest one skilled in the art to the direction of multiple C_1-C_4alkyl substituted piperidine. In response to Applicant's argument that the instant specification's disclosure of tetramethyl substitution on the piperidine ring is important because of sterically hindered amines (structure), the Examiner does not think such argument help applicant on the non-obviousness argument, because the references cited at the 1st paragraph, page 4 of the instant Specification (e.g. J. Pharmacol. Exp. Ther., **2000**, 292, 838-845) are known to the public before the filing date of the instant application, and in the public domain. On the other hand, such hindered amine was claimed preserved or even enhanced their antiarrhythmic activity, and gained a strong antioxidant effect, but does not teach the hinder amine enhancing the compound's inhibiting PARP enzyme, as the prior art and instant application disclosed. Therefore, the `271 patent's teaching indeed renders the instant application obviousness, without further side-by-side experimental comparative data support the improved properties and unexpected results. Accordingly, the rejection is maintained.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Chu whose telephone number is 571-272-5759. The examiner can normally be reached on 7:00 am - 3:30 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph M^{c}Kane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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